K000045 MAR 15 2000

ParaProducts Inc.
1431 Industrial Drive, Itasca, IL 60143
Phone (630) 250-7979 Fax (630) 250-8495
www.paraproducts.com

Premarket Notification

[510(k)] Summary

Submitter	
Company Name	ParaProducts Inc.
Address	1431 Industrial Drive Itasca, IL 60143
Phone Number	(630) 250-7979
Fax Number	(630) 250-8495
Contact Name, Title	James Flory, Secretary-Treasurer
Date of Preparation	January 5, 2000
Name of the Device	
Trade or Proprietary Name of Device	PosiTube
Common or Usual Name of Device	Esophageal Intubation Detection Device
Classification Name of Device	Tube, Tracheal – Accessory
Classification	
Class	Class II
Panel	Anesthesiology
Product Code	73BTR
Predicate Devices	
Substantially Equivalent Legally Marketed Devices	Esophageal Intubation Detection Devices
Substantially Equivalent Devices' 510(k) Numbers and Manufacturers	K930741 – Ambu Inc. K990556 – Wolfe Tory Medical, Inc.
Device Description	
A device that relies on the anatomical differences between the trachea and the esophagus to assist in verifying the proper placement of the endotracheal tube. When negative pressure is applied to the endotracheal tube, the rigid trachea remains open allowing free aspiration of air into the device, whereas the fibromuscular esophagus collapses around the endotracheal tube and prevents the aspiration of air.	

Indications for Use
To assist in verifying the proper placement of the endotracheal tube
Intended Use of the Device
This device is to be used as an adjunct to assess tracheal intubation. Its purpose is not to eliminate clinical judgment.

Technical Characteristics Comparison Between Device and Predicate Devices

Device	PosiTube	Predicate Devices
Design	Syringe-style esophageal intubation detection device with modified proximal end	Syringe-style esophageal intubation detection device
Principle of Operation	Relies on the anatomical differences between the trachea and the esophagus	Relies on the anatomical differences between the trachea and the esophagus
Materials	Polypropylene/Polyethyl-ene/Latex-free Elastomer	Polypropylene/Polyethyl-ene/Elastomer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2000

Mr. James Flory
ParaProducts Inc.
1431 Industrial Drive
Itasca, IL 60143

Re: K000045
PosiTube Esophageal Intubation Detection Device
Regulatory Class: II (two)
Product Code: 73 BTR
Dated: January 5, 2000
Received: January 7, 2000

Dear Mr. Flory:

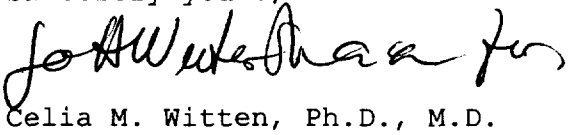
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000045

Device Name: PosiTube

Indications For Use:

To assist in verifying the proper placement of the endotracheal tube.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K000045